Complete Summary

GUIDELINE TITLE

Clinical policy guidelines.

BIBLIOGRAPHIC SOURCE(S)

National Abortion Federation (NAF). Clinical policy guidelines. Washington (DC): National Abortion Federation (NAF); 2006. 48 p. [81 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Clinical policy guidelines. Washington (DC): National Abortion Federation (NAF); 2005. 52 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On April 10, 2006, the U.S. Food and Drug Administration (FDA) released an update to the March 17, 2006 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On March 17, 2006, the U.S. Food and Drug Administration (FDA) issued a public health advisory to notify healthcare professionals of two additional deaths following medical abortion with mifepristone (Mifeprex) (see below for earlier FDA alerts). The FDA received verbal notification of the deaths in the United States from the manufacturer, Danco Laboratories. At this time FDA is investigating all circumstances associated with these cases and is not able to confirm the causes of death. However, all providers of medical abortion and their patients need to be aware of the specific circumstances and directions for use of this drug and all risks including sepsis when considering treatment. In particular, physicians and their patients should fully discuss early potential signs and symptoms that may warrant immediate medical evaluation. See the FDA Web site for more information.
- On November 4, 2005, the U.S. Food and Drug Administration (FDA) released an update to the July 20, 2005 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On July 20, 2005, Danco Laboratories and the FDA revised the BOXED WARNING and WARNINGS sections of the Prescribing Information, the Medication Guide and Patient Agreement to inform healthcare professionals of

four cases of septic deaths in the United States, all reported from California, from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. The bacteria causing sepsis has been identified in two of the cases as Clostridium sordellii. The two confirmed cases of Clostridium sordellii did not have the usual signs and symptoms of an infection. All providers of medical abortion and their patients need to be aware of the risks of sepsis. See the FDA Web site for more information.

Note from the National Guideline Clearinghouse and the National Abortion Federation: The guideline developers have reviewed the above-mentioned FDA advisory and note that their Clinical Practice Guideline Standards 2 & 3 for medical abortion comply with this alert by requiring that patients be fully informed of all risks and signs of complications.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unwanted pregnancy

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Endocrinology
Family Practice
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Hospitals
Managed Care Organizations

Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide a basis for ongoing quality assurance, help reduce unnecessary care and costs, help protect providers in malpractice suits, provide ongoing medical education, and encourage research in abortion services

TARGET POPULATION

Women with unwanted pregnancies

INTERVENTIONS AND PRACTICES CONSIDERED

1. Counseling and informed consent
2. Rhesus factor testing and rhesus immune globulin administration
3. Early medical abortion
4. First trimester surgical abortion
5. Second trimester abortion by dilation and extraction (D & E)
6. Second trimester abortion by medical induction
7. Anesthesia
8. Use of peri-operative antibiotics
9. Pre-operative endocarditis prophylaxis
10. Management of procedural complications
11. Postoperative care
12. Evaluation of evacuated uterine contents
13. Fetal tissue disposal
14. Emergency procedures

MAJOR OUTCOMES CONSIDERED

Quality evidence-based patient care

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Like its precursors, the 2006 edition of the National Abortion Foundation's Clinical Policy Guidelines establishes clinical policy guidelines which are developed by consensus, based on rigorous review of the relevant medical literature and known patient outcomes.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Guideline developers reviewed a published cost analysis.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of standards, recommendations, and options can be found at the end of the "Major Recommendations" field.

Who Should Perform Abortions?

Policy Statement: Abortion is a safe procedure when performed by qualified practitioners.

Standard 1: Abortion must be performed by licensed physicians or licensed/certified/registered midlevel clinicians trained in the provision of abortion care, in accordance with state law.

Standard 2: All personnel performing abortions must receive training in the performance of abortions and in the prevention, recognition, and management of complications.

Recommendation 0.1: When advanced practice clinicians such as physician assistants, nurse practitioners, or certified nurse midwives perform abortions, medical protocols should be in place that adhere to the clinician's scope of practice permitted by state law.

Recommendation 0.2: Appropriate referrals should be available for patients who cannot be cared for at your facility.

Counseling and Informed Consent

Policy Statement: Obtaining informed consent and assessing that the decision to have an abortion is made freely by the patient are essential parts of the abortion process.

Standard 1: Accurate information must be provided regarding the risks and benefits of abortion.

Option 1.01: This information may be provided either on an individual basis or in group sessions.

Standard 2: There must be documentation that the patient affirms that she understands the procedure and its alternatives; the potential risks, benefits, and complications; that her decision is uncoerced; and that she is prepared to have an abortion.

Recommendation 0.1: There should be an opportunity for discussion of the patient's feelings about the abortion decision.

Standard 3: A woman must undergo the abortion as expeditiously as possible in accordance with good medical practice.

Standard 4: Information about birth control must be available to patients at the facility.

Standard 5: All reasonable precautions must be taken to ensure the patient's confidentiality.

Rhesus Factor (Rh) Testing and Rh Immune Globulin Administration

Policy Statement: Rhesus factor (Rh) alloimmunization is a significant health risk to Rh(-) women undergoing abortion.

Standard 1: Rh status must be documented in all women undergoing abortion. This documentation may be obtained by onsite testing or outside medical source. Du testing is not required.

Standard 2: Rh immune globulin administration must be offered to Rh(-) women and documented.

Standard 3: If Rh immune globulin is not administered in the facility, one of the following is required: informed waiver signed by a patient who refuses Rh immune globulin or documentation of other arrangements for administration.

Early Medical Abortion

Policy Statement: Medical induction is an effective method for early abortion. Adequate counseling and follow-up care will enhance its safety and acceptability.

Standard 1: The patient must be informed about the need for follow-up contact to ensure that she is no longer pregnant.

Standard 2: The patient must be informed about the efficacy, side effects, and risks, especially excessive bleeding and teratogenicity, associated with the medications to be used.

Standard 3: Patient instructions must include information about use of medications at home and symptoms of abortion complications.

Recommendation 3.1: Written instructions should be given to all patients.

Standard 4: The patient's willingness to consent to surgical abortion if medical abortion fails must be documented.

Standard 5: The facility must provide an emergency contact service on a 24-hour basis and must offer or assure referral for uterine aspiration if indicated.

Standard 6: Gestational age must be documented.

Recommendation 6.1: Ultrasonography, using a consistent and published table of fetal measurements, should be used to confirm and document gestational age

when physical exam and the last menstrual period (LMP) are substantially discordant.

Option 6.01: Ultrasonography may be used routinely.

Standard 7: Patient comfort level during the abortion procedure must be considered.

Option 7.01: Analgesia or other comfort measures may be used as needed unless there are contraindications.

Standard 8: Completion of the abortion must be documented by ultrasonography, human chorionic gonadotropin (hCG) testing, or by clinical means.

Recommendation 8.1: Ultrasonography should be used to evaluate completion of the abortion when expected bleeding does not occur after medications.

Option 8.01: Ultrasonography may be used routinely.

Standard 9: Rh immune globulin must be offered in accordance with Rh Guidelines. See the Clinical Policy Guidelines on "Rh Testing and Rh Immune Globulin Administration" (above).

Standard 10: The patient must be evaluated for ectopic pregnancy if:

a. Transvaginal ultrasonography shows no intrauterine pregnancy and serum quantitative hCG exceeds 2,000 mIU/mL (note: all hCG values used in this document are based on the Third International Standard, originally referred to as the First International Reference Preparation) OR
b. Abdominal ultrasonography shows no intrauterine pregnancy and serum quantitative hCG exceeds 3,600 mIU/mL
c. A suspicious adnexal mass is found on ultrasound or pelvic exam
d. No pre-abortion sonography demonstrating an intrauterine pregnancy (IUP) has been performed, and there is minimal or no bleeding in response to medications

Standard 11: When a patient with a positive pregnancy test presents with vaginal bleeding and/or pelvic pain, ectopic pregnancy must be considered.

Option 5.01: Evaluation may include:

a. Sonography
b. Uterine aspiration
c. Serial quantitative hCGs

Experience would suggest:

- Each provider site should have a written protocol to evaluate ectopic pregnancy.
- All clinicians at the site should be familiar with the protocol.

- Patients with a positive pregnancy test in whom the pregnancy cannot be localized should be advised that an ectopic pregnancy cannot be ruled-out.
- Each provider site should have a patient education handout describing ectopic warning signs and documentation that the patient has received this handout.
- Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols

Recommendation 0.1: When methotrexate with misoprostol is used, the patient's gestation should be no greater than 49 days.

Recommendation 0.2: When mifepristone and oral misoprostol is used, the patient's gestation should be no greater than 49 days. (Mifepristone must be used in an evidence-based regimen.)

Recommendation 0.3: When mifepristone and vaginal misoprostol is used, the patient's gestation should be no greater than 63 days. (Mifepristone must be used in an evidence-based regimen.)

First Trimester Surgical Abortion

Policy Statement: Abortion is one of the safest surgical procedures in the United States today. The following guidelines enhance this safety.

Pre-Operative Procedure

Standard 1: Pertinent medical history must be obtained and documented.

Standard 2: Confirmation of pregnancy must be documented.

Standard 3: Gestational age must be verified and documented.

Option 3.01: Ultrasonography, using a consistent and published table of fetal measurements, can be of clinical value in verifying intrauterine pregnancy and gestational age.

Standard 4: The patient must be evaluated for ectopic pregnancy if:

a. Transvaginal ultrasonography shows no intrauterine pregnancy and serum quantitative hCG exceeds 2,000 mIU/mL (note: all hCG values used in this document are based on the Third International Standard, originally referred to as the First International Reference Preparation) OR
b. Abdominal ultrasonography shows no intrauterine pregnancy and serum quantitative hCG exceeds 3,600 mIU/mL
c. A suspicious adnexal mass is found on ultrasound or pelvic exam

Standard 5: When a patient with a positive pregnancy test presents with vaginal bleeding and/or pelvic pain, ectopic pregnancy must be considered.

Option 5.01: Evaluation may include:

a. Sonography

b. Uterine aspiration
c. Serial quantitative hCG

Experience would suggest:

- Each provider site should have a written protocol to evaluate ectopic pregnancy.
- All clinicians at the site should be familiar with the protocol.
- Patients with a positive pregnancy test in whom the pregnancy cannot be localized should be advised that an ectopic pregnancy cannot be ruled-out.
- Each provider site should have a patient education handout describing ectopic warning signs and documentation that the patient has received this handout.
- Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols

Recommendation 0.1: Hematocrit (Hct) or hemoglobin (Hgb) should be obtained in women with a history of significant anemia. (Note: By establishing a balance sheet of risks, costs, and outcomes, it was discovered that a pre-operative Hct was of relatively questionable value statistically in preventing morbidity and mortality in a healthy woman in the first trimester with no history of anemia or major disease process.)

Recommendation 0.2: Vital signs (e.g., blood pressure, pulse, and temperature) and physical exam should be done as indicated by medical history and patient symptoms.

Operative Procedure

Standard 6: Patient comfort level during the procedure must be considered.

Recommendation 6.1: Analgesic or other comfort measures should be offered unless there are contraindications. See the Clinical Policy Guidelines on "Anesthesia" (below).

Standard 7: All instruments entering the uterine cavity must be sterile.

Option 0.01: The vagina may be cleansed with a bactericidal agent.

Recommendation 0.3: The cervix should be dilated gently and gradually.

Option 0.31: Adequate dilation may be achieved by osmotic dilators or misoprostol.

Option 0.32: At very early gestational age, cervical dilation may be facilitated by delaying the procedure.

Option 0.02: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to verify an empty uterus, and to verify an intact uterus.

Post-Operative Procedure

Standard 8: Completion of the procedure must be verified and documented. See the Clinical Policy Guidelines on "Evaluation of Evacuated Uterine Contents" (below).

Standard 9: Rh immune globulin must be offered per Rh policy guidelines. See the Clinical Policy Guidelines on "Rh Testing and Rh Immune Globulin Administration" (above).

Option 9.01: Rh immune globulin may be injected into the cervix for Rh(-) patients.

Standard 10: Clinical Policy Guidelines for "Postoperative Care" (below) must be followed.

Second Trimester Abortion by Dilation and Evacuation

Policy Statement: Second trimester abortion by dilation and evacuation (D&E) is a safe outpatient surgical procedure when performed by appropriately trained clinicians in medical offices, freestanding clinics, and ambulatory surgery centers. For the purposes of these guidelines, second trimester begins at 15 weeks from the LMP. As gestational age increases, complications and risks increase.

Pre-Operative Procedure

Standard 1: Pertinent medical history must be obtained and documented.

Option 0.01: A patient with a low-lying placenta (confirmed by a sonogram) and prior uterine scarring may be evaluated for placenta previa.

Recommendation 0.1: Physical examination should be done as indicated by medical history and patient symptoms.

Standard 2: Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks from the LMP.

Recommendation 0.2: A preoperative Hgb or Hct should be done.

Operative Procedure

Standard 3: Patient comfort level during the abortion procedure must be considered.

Recommendation 3.1: Analgesic or other comfort agents should be offered unless there are contraindications. See Clinical Policy Guidelines on "Anesthesia" (below).

Standard 4: Appropriate dilation of the cervix must be obtained.

Recommendation 4.1: Dilation should be achieved gently and gradually.

Recommendation 4.2: Osmotic dilators or misoprostol should be used to facilitate adequate dilation.

Standard 5: When osmotic dilators are used, a physician must be available for emergency care prior to the scheduled procedure.

Option 0.02: In second trimester abortions, intra-amniotic or intra-fetal injection may be given (refer to original guideline document for dosage instructions).

Recommendation 0.02.1: When Option 0.02 is followed, these injections should be given at the time of laminaria insertion.

Option 0.03: Fetal cranial decompression may facilitate evacuation of the uterus.

Standard 6: All instruments entering uterine cavity must be sterile.

Standard 7: Uterine forceps appropriate for second trimester abortion must be available.

Recommendation 0.3: Oxytocics should be available to aid in control of uterine bleeding.

Recommendation 0.4: Vasopressin should be used in the cervical anesthetic solution.

Option 0.04: Intraoperative ultrasonography can be of value to locate fetal parts and aid in their extraction, to verify an empty uterus, and to verify an intact uterus.

Option 0.05: Intravenous (IV) access may be established prior to evacuation.

Postoperative Procedure

Standard 8: Completion of the procedure must be verified and documented by the operator. See Clinical Policy Guidelines on "Evaluation of Evacuated Uterine Contents" (below).

Standard 9: Clinical Policy Guidelines for "Postoperative Care" (below) must be followed.

Option 0.06: Uterotonic agents may be prescribed.

Second Trimester Abortion by Medical Induction

Policy Statement: Medical induction is a safe and effective method for termination of pregnancies beyond the first trimester in appropriate clinical settings by trained clinicians. For the purposes of these guidelines, the second trimester begins at 15 weeks LMP. As gestational age increases, complications and risks increase.

Standard 1: Pertinent medical history must be obtained and documented.

Recommendation 0.1: Physical examination should be done as indicated by medical history and patient symptoms.

Standard 2: Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks LMP.

Option 0.01: A patient with a low-lying placenta (confirmed by sonogram) and prior uterine scarring may be further evaluated for placenta previa.

Recommendation 0.2: A pre-abortion Hgb or Hct should be done.

Standard 3: Patient comfort level during the abortion procedure must be considered.

Recommendation 3.1: Analgesic or other comfort measures should be offered unless there are contraindications. See Clinical Policy Guidelines on "Anesthesia" (below).

Recommendation 0.03: In order to reduce the induction-to-abortion interval and the likelihood of complications such as uterine rupture, the cervix should be pretreated. (See Discussion in the original guideline document).

Standard 4: Patients must be advised that administration of prostaglandins for priming or induction may precipitate rapid onset of uterine contractions and expulsion.

Option 0.02: In second trimester abortions, intra-amniotic or intra-fetal injection may be given (refer to the original guideline document for safe, effective regimens).

Option 0.03: IV access may be established prior to expulsion.

Standard 5: All instruments entering uterine cavity must be sterile.

Standard 6: Uterine forceps appropriate for second trimester abortion must be available.

Standard 7: Patients must be given detailed instructions to contact the health care facility when regular contractions begin.

Recommendation 7.1: Written instructions should be given to all patients.

Standard 8: Once regular contractions have been confirmed, patients must be observed by a health care worker trained to monitor contractions and expulsion.

Standard 9: A physician must be available for emergency care from initiation of cervical pretreatment until post-abortion discharge.

Recommendation 0.4: Oxytocics should be available to aid in control of uterine bleeding.

Standard 10: A licensed clinician capable of performing a timely curettage must be available until post-abortion discharge. (The incidence of retained placenta with mid-trimester induction abortion has been reported in 10 to 40% of cases.)

Standard 11: Completion of the procedure must be verified and documented by the operator. See Clinical Policy Guidelines on "Evaluation of Evacuated Uterine Contents" (below).

Standard 12: Clinical Policy Guidelines for "Postoperative Care" (below) must be followed.

Option 0.04: Uterotonic agents may be prescribed.

Anesthesia

Policy Statement: The use of anesthesia and/or analgesia can minimize pain and anxiety in abortion procedures but has certain risks in addition to its benefits.

Personnel and Monitoring

Standard 1: When conscious sedation, deep sedation, or general anesthesia is used, monitoring of the patient's level of consciousness must be documented.

Standard 2: When conscious sedation or local anesthesia is used, the practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be appropriately trained.

Standard 3: When conscious sedation is used, a person other than the clinician, trained to monitor appropriate physiological parameters, must be present.

Recommendation 3.1: During conscious sedation the patient should be checked frequently for verbal responses.

Standard 4: The personnel administering conscious sedation must recognize that conscious sedation may lead to deep sedation with hypoventilation and be prepared to provide respiratory support. See the Clinical Policy Guidelines on "Emergency Procedures" (below).

Standard 5: The supervising practitioner must be immediately available when conscious sedation is administered.

Standard 6: When conscious sedation is used, monitoring must be of a degree that can be expected to detect the respiratory, cardiovascular, or neurological effects of the drugs being used.

Option 6.01: Pulse oximetry may be used to enhance this monitoring.

Recommendation 0.1: During conscious sedation or local anesthesia, IV access should be maintained for patients in American Society of Anesthesiologists (ASA) Classification of Physical Status P-3, P-4, and P-5 (see page 27 of the original guideline document).

Standard 7: The practitioner administering general anesthesia or deep sedation must be certified according to applicable state requirements.

Standard 8: The practitioner administering general anesthesia or deep sedation must not be the practitioner performing the abortion.

Standard 9: For general anesthesia and deep sedation, the patient's oxygenation, ventilation, circulation, and temperature must be continually evaluated as prescribed in the ASA "Standards for Basic Intra-Operative Monitoring" (see pages 29 to 31 of the original guideline document).

Recommendation 9.1: When deep sedation and/or general anesthesia are used, IV access should be maintained according to ASA guidelines.

Standard 10: The use of nitrous oxide/oxygen (N_2O/O_2) must follow guidelines for at least conscious sedation.

Standard 11: Equipment for the delivery of N_2O/O_2 must:

1. Provide a concentration of N_2O of no more than 70% inspired
2. Provide a maximum of 100% and minimum of 30% O_2 conc.
3. Be outfitted with an O_2 analyzer
4. Be checked and calibrated regularly

Standard 12: When conscious sedation, deep sedation, or general anesthesia is used, there must be documentation that the patient has been warned of possible transient mental impairment.

Facilities and Equipment

See "Emergency Procedures" guideline (below).

Use of Peri-operative Antibiotics at the Time of Surgical Abortion

Policy Statement: Prevention and treatment of infection will reduce post-abortion morbidity.

Recommendation 0.1: All women should receive antibiotics at the time of surgical abortion.

Recommendation 0.2: Therapeutic doses of antibiotics should be considered for high-risk patients.

Recommendation 0.3: For documented infections, the U.S. Centers for Disease Control and Prevention (CDC) guidelines should be followed. Current treatment guidelines include doxycycline, azithromycin, erythromycin, ofloxacin, or

levofloxacin for chlamydia; and metronidazole for bacterial vaginosis (see page 33 of the original guideline document for dosing information).

Option 0.01: Antibiotics may be initiated at the time of insertion of osmotic dilators.

Option 0.02: Patients with non-cardiac prostheses may be given peri-operative antibiotics. "It is the opinion of the American Academy of Oral Medicine that there is insufficient scientific evidence to support routine antibiotic prophylaxis for patients with prosthetic joints who are receiving dental care." (Eskinazi D, Rathburn W. Is systematic antimicrobial prophylaxis justified in dental patients with prosthetic joints? Oral Surg Oral Med Oral Pathol 1988;66:43).

Pre-operative Endocarditis Prophylaxis at the Time of Surgical Abortion

Policy Statement: Endocarditis is a potential risk of surgical procedures.

Option 0.01: Patients with a prosthetic heart valve, previous bacterial endocarditis, or surgically constructed pulmonary shunt may be given pre-operative prophylactic antibiotics.

Option 0.02: Patients with mitral valve prolapse with a murmur may be given oral antibiotics prior to the procedure.

Complications: Bleeding

Policy Statement: One of the most serious complications of an abortion procedure is hemorrhage. Early recognition of the source of bleeding can reduce morbidity and mortality.

Pre-Operative Bleeding

Recommendation 0.1: An ectopic pregnancy or spontaneous abortion should be considered.

Peri-operative Bleeding

Standard 1: When there is excessive bleeding, the surgeon must institute measures to identify the etiology of the bleeding and control it.

Recommendation 1.1: The surgeon should consider incomplete procedure, atony, fibroids, lacerations, perforations, placenta accreta, cervical or cornual pregnancy, coagulopathy.

Option 1.01: Ultrasonography may be useful to determine whether the uterus is empty and to detect occult bleeding.

Option 1.02: When a cervical bleeding source is suspected, hemostasis may be achieved by compressing the cervix at the lateral fornices with ring forceps or placing a suture.

Option 1.03: When atony is suspected, uterine massage and uterotonics (methergine [intracervical or intramuscular (IM)]; oxytocin [intracervical, IM, or IV]; prostaglandins [e.g., Prostin, intracervical or IM]) may be useful.

Option 1.04: When coagulopathy is suspected, blood may be drawn for coagulation parameters.

Recommendation 0.2: When excessive bleeding continues, the following measures should be instituted: monitor and document blood pressure, pulse, clinical status; uterotonics; establish IV access; initiate appropriate volume replacement; prepare for transfer to a hospital facility if necessary.

Standard 2: The patient must be transferred to a hospital facility when the bleeding does not respond to therapeutic measures or when the patient is hemodynamically unstable.

Delayed Bleeding

Standard 3: When a patient reports excessive bleeding (saturation of more than one pad per hour for more than three hours) after discharge from the abortion facility, she must be evaluated by that facility or an emergency contact service.

Complications: Perforation

Policy Statement: Uterine perforation is a complication of abortion that can lead to significant morbidity.

Standard 1: If, in the clinician's judgment, an instrument passes farther than expected, then uterine perforation must be considered.

Standard 2: If a perforation occurs, even if the patient is asymptomatic, close observation and follow-up must be done.

Option 2.01: Antibiotic coverage may be instituted.

Option 2.02: Uterotonics may be administered.

Option 2.03: The patient may be transferred to a hospital.

Option 2.04: If a perforation occurs and the pregnancy has not been disrupted, the completion of the procedure may occur immediately, after a delay, or by referral to another provider.

Recommendation 2.1: If a perforation occurs and the pregnancy has been disrupted, the abortion should be completed as soon as feasible.

Option 2.05: The uterine evacuation may be completed under direct ultrasonography.

Option 2.06: The abortion may be completed under laparoscopic visualization.

Option 2.07: Re-identification of the uterine cavity may be performed and the abortion completed.

Standard 3: The patient must be hospitalized for definitive care if intra-abdominal viscera are detected in the uterine cavity, cervix, vagina, suction tubing, or on tissue examination; fetal parts are detected in the abdominal cavity; expanding intra-abdominal hematoma is detected; or hemodynamic instability is present.

Standard 4: When uterine perforation is suspected and the cannula has been inserted into the uterine cavity, suction must be released immediately before the cannula is withdrawn.

Postoperative Care

Policy Statement: Most serious abortion complications are detectable in the immediate postoperative period. Appropriate and accessible follow-up care is essential to patients' well-being.

Standard 1: Completion of the abortion must be verified and documented. See Clinical Policy Guidelines on "Evaluation of Evacuated Uterine Contents" (below).

Standard 2: Rh immune globulin must be offered in accordance with Rh guidelines. See Clinical Policy Guidelines on "Rh Testing and Rh Immune Globulin Administration" (above).

Standard 3: All patients must be observed during the recovery period by a health care worker trained in postoperative care.

Standard 4: A clinician must remain in the facility until all patients are medically stable. (Clinician is defined as a physician, nurse practitioner, physician assistant, or nurse midwife.)

Standard 5: The following criteria must be documented prior to discharge: the patient must be ambulatory with a stable blood pressure and pulse, and bleeding and pain must be controlled.

Standard 6: The patient must be given instructions outlining the signs and symptoms of postoperative complications.

Recommendation 6.1: Written instructions should be given to all patients.

Standard 7: The facility must provide an emergency contact service on a 24-hour basis where calls are triaged in accordance with appropriate law. The facility must assure physician referral if indicated.

Option 0.01: A feedback form may be sent home with the patient to help gather medical, psychological, and social information that may have affected her outcome.

Evaluation of Evacuated Uterine Contents

Policy Statement: Complete removal and identification of products of conception help prevent complications of abortion.

Standard 1: Evacuated uterine contents must be examined before the woman leaves the facility.

Recommendation 1.1: In first trimester terminations, flotation of tissue with backlighting should be used to identify products of conception, including gestational sac.

Option 1.11: Pathological examination of evacuated uterine contents may be performed.

Standard 2: When insufficient tissue or incomplete products of conception are obtained, the patient must be reevaluated.

Recommendation 2.1: Follow-up pelvic ultrasonographic examination should be considered.

Recommendation 2.2: Resuctioning should be considered.

Standard 3: If insufficient tissue is present after adequate patient evaluation, a protocol to rule out ectopic pregnancy must be followed, and the patient must be informed of symptoms and dangers of ectopic pregnancy.

Recommendation 3.1: If the uterine cavity is determined to be empty, serial quantitative hCG or sensitive urine pregnancy test should be measured. (Sensitive urine pregnancy test is positive at 50 MIU of beta-hCG.)

Standard 4: The patient must not be released from follow-up care until the diagnosis of ectopic pregnancy has been excluded or an appropriate referral has been documented.

Recommendation 4.1: A 48-hour post-procedure serum quantitative hCG test should be done. If there is a decrease of 50% or more, no further ectopic follow up is necessary.

Recommendation 4.2: If 48-hour post-procedure serum quantitative hCG testing shows no change, or a subnormal increase in value, ectopic pregnancy evaluation and definitive treatment should be instituted and documented, or a referral made and documented.

Standard 5: In second trimester abortions, placenta and all major fetal parts must be removed from the uterus.

Recommendation 5.1: If the above are not identified, the following should be considered: ultrasonographic evaluation, intravenous pitocin administration, repeat uterine exploration.

Recommendation 5.2: The clinician should continue care of the patient until completion of the abortion has been determined.

Option 0.01: Intraoperative ultrasonographic guidance may be used to facilitate uterine exploration.

Fetal Tissue Disposal

Policy Statement: The improper disposal of tissue can lead to spread of infectious disease and can increase the risk of theft or misplacement of tissue. Because of the possible infectious nature of tissue removed during the abortion procedure, guidelines for proper fetal tissue disposal are established.

Standard 1: All surgically removed tissue must be considered biohazardous and be disposed of in accordance with applicable local, state, and federal regulations. A proper protocol for tissue disposal must be in place.

Recommendation 1.1: There should be medically adequate protection of personnel.

Recommendation 1.2: There should be proper handling and storage of tissue using either biohazard disposal service; licensed pathology laboratory; or on-site disposal where permitted by regulations.

Emergency Procedures

Policy Statement: Optimal management of abortion emergencies reduces morbidity.

Standard 1: Functioning equipment and current medications must be available on site to handle medical emergencies and must include an O_2 delivery system, oral airways, uterotonics, and epinephrine.

Recommendation 1.1: Facilities should have a specified area for emergency equipment to include oxygen, medications, and supplies.

Recommendation 1.2: Protocols should be in place to ensure ongoing training of staff in the use of emergency equipment, the management of emergencies, and the indications for emergency transport.

Recommendation 1.3: Medications should include IV crystalloids and, in clinics using IV sedation, narcotic antagonists.

Standard 2: When abortion procedures are being performed, a current cardiopulmonary resuscitation (CPR)-certified staff member must be available on-site for emergency care.

Recommendation 2.1: All medical staff should be current CPR-certified.

Option 0.1: The following supplies may be used:

Type of Emergency (Prevention, Treatment)

Anaphylaxis (Corticosteroids, epinephrine)
Allergic reactions (Diphenhydramine [Benadryl], epinephrine, albuterol inhalers)
Respiratory arrest (Oxygen, suction, Ambu bag, airways)
Hemorrhage, shock (IV crystalloid [normal saline or Ringers lactate], uterotonics)
Cardiac arrest (CPR)
Seizure (Diazepam [Valium], midazolam [Versed])
Respiratory depression (Pulse oximeter)

Definitions:

Standards are intended to be applied rigidly. They must be followed in virtually all cases. Exceptions will be rare and difficult to justify.

Recommendations are steering in nature. They do not have the force of standards, but when not adhered to, there should be documented, rational clinical justification. They allow some latitude in clinical management.

Options are neutral with respect to a treatment choice. They merely note that different interventions are available and that different people make different choices. They may contribute to the educational process, and they require no justification.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Enhance the quality and safety of abortion services
- Reduce unnecessary care and costs

POTENTIAL HARMS

- Complications of abortions include bleeding and uterine perforation.
- All medications used in anesthesia have the potential for serious risk. This risk may be reduced to a minimum by adherence to established practice guidelines. Guidelines developed by other organizations concern themselves with anesthesia delivered primarily in hospital settings and to patients varying widely in age and general health. Abortion patients, however, are younger and rarely have significant health problems. Nonetheless, anesthesia

complications are an increasing proportion of total abortion morbidity and mortality.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The original guideline document specifically addresses the use of conventional anesthesia. It is recognized that patient comfort and reduced anxiety are not dependent only on pharmacologic measures, but are significantly affected by patient counseling and by a supportive staff. It is also recognized that there is a wide range of alternative modalities (such as acupuncture, yoga, hypnosis) that are helpful for many patients. The focus of the original guidelines, however, is on the monitoring necessary for the safe and effective use of pharmacologic methods generally used in outpatient abortion facilities.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Abortion Federation (NAF). Clinical policy guidelines. Washington (DC): National Abortion Federation (NAF); 2006. 48 p. [81 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2006)

GUIDELINE DEVELOPER(S)

National Abortion Federation - Professional Association

SOURCE(S) OF FUNDING

National Abortion Federation (NAF)

GUIDELINE COMMITTEE

Clinical Policy Guidelines Committee, National Abortion Federation Board of Directors

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Participating Committee members change periodically, but include or have included: James Armstrong, MD; Rachel Atkins, PA; Curtis Boyd, MD; Susan Cahill, PA-C; Bruce Ferguson, MD; Herbert Jones, MD; Roselyn Kade , MD; L. Steve Lichtenberg, MD; Deborah Oyer, MD; Maureen Paul, MD; Suzanne T. Poppema, MD; Gary Prohaska, MD; Pablo Rodriguez, MD; Eric Schaff, MD; Bernard Smith, MD; Pat Smith, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Clinical policy guidelines. Washington (DC): National Abortion Federation (NAF); 2005. 52 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Abortion Federation Web site.

Print copies: Available from the National Abortion Federation (NAF), 1755 Massachusetts Ave, NW, Ste. 600, Washington DC 20036; www.prochoice.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 28, 1999. The information was verified by the guideline developer on May 28, 1999. The information in this summary was subsequently updated to reflect changes published in 2000, 2001, 2002, 2003, and 2004. This summary was updated most recently on February 9, 2005. The information was verified by the guideline developer on February 10, 2005. This summary was updated by ECRI on July 21, 2005 following the Food and Drug Administration (FDA) advisory on Mifeprex (mifepristone). This summary was updated by ECRI on March 7, 2006 following the updated FDA advisory on Mifeprex (mifepristone). This summary was updated by ECRI on March 24, 2006 following another updated FDA advisory on Mifeprex (mifepristone). This summary was updated on April 19, 2006. The updated information was verified by the guideline developer on May 9, 2006.

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